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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,326	09/30/2003	Sigmund Kulessa	COD0183USNP	6484

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BOUCHELLE, LAURA A	
ART UNIT	**PAPER NUMBER**
3763	

MAIL DATE	DELIVERY MODE
10/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/676,326	KULESSA, SIGMUND	
	Examiner	Art Unit	
	LAURA A. BOUCHELLE	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,15-24,26-36,38-42,44-50 and 52-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-13,15-24,26-36,38-42,44-50 and 52-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3-13, 15-24, 26-36, 38-42, 44-50,52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tucker et al (US 4,193,397) in view of Karp (US 2003/0133358) in view of Blischak et al (US 6620151).

3. Tucker discloses an infusion apparatus that includes a medication reservoir, a carrier reservoir, a mixing chamber 88, a medication flow path, a carrier flow path, a medication pump system, and an outlet port. The device also includes a medication flow restrictor, and a carrier flow restrictor (col. 5, line 53 – col. 6, line 13, col. 7, lines 28-33). These restrictors can be more or less restrictive than one another. The device also includes a power cell.

4. Tucker discloses that the device allows the fluid from the first and second reservoir to be conveyed to the mixing chamber in different concentrations (abstract) and the configuration allows for the flow from the reservoirs to complement and supplement each other (col. 3, lines 12-13, 28-30).

5. Claims 1, 19, 42, 50 differ from Tucker in calling for the mixing chamber to be a microfluidic chip having a capillary pathway disposed in a serpentine pattern. Claims 15 and 16 call for the flow restrictors to be a microfluidic chip. Tucker discloses that mixing chamber 88 serves to mix multiple fluids and deliver the mixture to the patient (col. 9, lines 55-65). Karp

teaches a microfluidic chip for mixing multiple fluid steams without a need for moving parts. The chip has a capillary pathway in a serpentine pattern. See Figs. 13 A-E. This configuration allows for complete mixing of the two fluids in a compact area without the use of moving parts that add to the cost of manufacture as well as the life of the device. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Tucker to include the microfluidic chip as taught by Karp to allow for better mixing of the two fluids without adding any complicated structures or mechanisms to the device.

6. Claims 1, 19, 42 further differ from the teachings above in calling for a bolus port located between the mixing chamber and the outlet port. Claim 50 calls for the step of introducing a bolus dose. Blischak teaches that it is common practice in the art of implantable infusion pumps to include a bolus port downstream of the reservoir delivery lines or flow restrictors. This configuration has many advantages such as flushing of the downstream line, delivery of a prescribed dosage which may be a greater volume or higher rate than can be accommodated by the flow restrictor (or mixing chamber), performing troubleshooting or diagnostic procedures, or possibly even extraction of fluid from the patient (col. 6, lines 30-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Tucker to include a bolus port between the mixing chamber and the outlet port as taught by Blischak to allow for infusion of medicaments at a volume or rate higher than allowed by the mixing chamber.

Response to Arguments

7. Applicant's arguments filed 7/28/09 have been fully considered but they are not persuasive. Applicant argues that Tucker's bolus dose is never mixed and diluted with the basal

dose. The examiner disagrees. Tucker clearly discloses that the bolus and basal dose are mixed. The examiner points applicant to col. 9, lines 55-65 where Tucker discloses that "in chamber 88, the bolus infusate mixes with and supplements the basal infusate still arriving form the basal reservoir…" Furthermore, throughout the disclosure Tucker uses the terms "mixing chamber" and describes the basal and bolus doses as "supplementing" and "complementing" each other as they each flow from their respective reservoirs simultaneously (col. 3, lines 10-30).

8. Applicant argues that since Tucker includes a bolus port it would not have been obvious to include a second bolus port between the mixing chamber and the outlet. The examiner disagrees. Tucker uses the terms basal and bolus for the reservoirs. In reality, these reservoirs simply contain two different concentrations of a fluid. The fluid flowing from the "bolus" reservoir is still limited by the flow restrictors and the mixing chambers. Blischak teaches that it is desirable to include a bolus port outside of all flow restrictors or other structures that may limit the rate or volume of flow to allow for delivery of fluid outside of the limitations of the pump. Focusing only on the terms used by Tucker, yes it does seems as though the device already contains a bolus port, however upon further inspection, it is clear that the bolus reservoir of Tucker functions more as a supplemental drug reservoir and not a "bolus" reservoir in the generally accepted meaning. The bolus reservoir of Tucker has a different function than the bolus port of Blischak and therefore given the teachings of Blischak it would have been obvious to add a bolus port to Tucker.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/Laura A Bouchelle/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763